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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,296	06/21/2001	Hsien-Jue (Steve) Chu	AM100221	6853

25291 7590 02/14/2003

WYETH
PATENT LAW GROUP
FIVE GIRALDA FARMS
MADISON, NJ 07940

EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 02/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/887,296	Chu et al.
Examiner	**Art Unit**
S. Devi, Ph.D.	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Oct 25, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above, claim(s) *11-26* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-10* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *1 and 2*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election

1) Acknowledgment is made of Applicants' election filed 07/22/02 (paper no. 4) and 10/25/02 (paper no. 6), with traverse, of invention II, claims 1-10, and the election of bacterium species of claim 1, in response to the restriction and the species election requirement mailed 06/20/02 (paper no. 3). Applicants' traversal is on the grounds that the restriction requirement is not capable of being understood with regard to the classification and subclassification. Applicants provide parts of the Manual of Classification in their response along with several 'Notes'. Applicants state that invention III is classified in class 184.1, and then relate the same to the class of lubrication. Applicants state that they have considered the possibility that the intended subclass was 184.1 of class 424. Applicants state that it is unclear where the distinction between the methods of invention II and III resides. Applicants acknowledge that under 35 U.S.C. 121, two or more independent and distinct inventions in one application may be restricted to one of the inventions. Applicants cite MPEP 802.01 and state that inventions are independent if there is no disclosed relationship between the two or more subjects disclosed. Applicants acknowledge that the term 'distinct' means that two or more subjects as disclosed are related but are capable of separate manufacture, use or sale as claimed and are patentable over each other. Applicants cite MPEP 808.02 and submit that even with patentably distinct inventions, restriction is not required unless one of the following reasons appear: separate classification; separate status in art; or different filed of search. Applicants further state that under patent Office examining procedures, if the search and examination of an entire application can be made without a serious burden, the Examiner is encouraged to examine it on the merits, even though it includes claims to distinct or independent inventions. Applicants further cite several issued patents and point to fields of search therein. Applicants opine that classifications are merely just a convenience encompass more than one subclass.

Applicants' arguments have been carefully considered, but are non-persuasive. Applicants have correctly noted an inadvertent error in the restriction requirement wherein invention III was indicated as belonging to the class 184. 1, instead of class 424, subclass 184.1. The restriction requirement in the instant case follows all appropriate statutes and regulatory principles and

conforms closely with guidelines provided by MPEP, Chapter 800. With regard to the burden, Applicants are correct that the term "distinct" is defined to mean that two or more subjects as disclosed are related, for example, for example as product and method of use, but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (MPEP 802.01). In the instant case, the product of invention I is capable of separate use, i.e., a non-vaccine use as a diagnostic reagent. An 'antigen selected from the group consisting of a bacterium and virus' broadly encompasses live or killed bacterium or virus as well as an isolated or non-isolated antigen of a bacterium or virus. As set forth in the restriction requirement mailed 06/20/02 (paper no. 3), invention I and inventions II and III are related as product and processes of using the product. M.P.E.P 806.05(h) permits separation of the two inventions if the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the vaccine of invention I can be used in a materially different, non-immunization process, for example, an *in vitro* diagnostic test as a coating antigen. Applicants have not presented any arguments showing that the claimed product cannot be used in a materially different non-immunization process. Furthermore, the methods of inventions II and III differ from one another in method steps and ultimate goals accomplished. The method of invention II comprises three steps and is meant to provide protection against a disease or infection by the antigen, whereas the method of invention III includes four steps and is meant to induce the increased intake of the oral vaccine with the flavorant.

With regard to burden of search and examination, MPEP 803 states that a restriction is proper between patentably distinct inventions where the inventions are (1) independent or distinct as claimed and (2) a serious search and *examination burden* is placed on the Examiner if restriction is not required. In the instant application, in addition to a search burden that necessitates searches of issued US patents under separate classes/subclasses, an examination burden is apparent, since the legal standards applicable for method claims are distinct from those applicable for product claims. Furthermore, Applicants should note that divergent classification or subclassification has traditionally been utilized as one indicator that burden exists sufficient to

warrant restriction. The classification system has no statutory recognition as to whether inventions are independent and distinct. For example, each class and subclass is comprised of numerous completely independent and distinct patented inventions. Further, it should be noted that the non-patent literature search, particularly in this art, is non-coextensive. Clearly, different searches and examination issues are involved in the examination of each invention in the instant application. For these reasons, the restriction set forth in the Office Action mailed 06/20/02 (paper no. 3) is proper and is hereby made FINAL.

Had Applicants elected the product claims (invention I), the claims drawn to methods of using the product (invention II) would have been kept pending pursuant to the rejoinder provisions of M.P.E.P 821.04 and would have been rejoined with the elected product claims, if and when the latter were deemed allowable.

Information Disclosure Statements

2) Acknowledgment is made of Applicants' information disclosure statements filed 06/21/01 and 05/23/02 (paper no. 2). As an attachment to this Office Action (paper no. 7).

Status of Claims

3) Claims 1-26 are pending.

Claims 11-26 have been withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Claims 1-10 are under examination.

Priority

4) The instant application claims priority to the provisional application SN 60/215,359, filed 06/30/2000.

Abstract

5) The abstract of the disclosure is objected to because the number of words contained in the abstract exceeds the number of words permitted, i.e., 150 words. Correction is required. See MPEP § 608.01(b).

Specification - Informalities

6) The specification is objected to for the following reasons:

(a) The first paragraph of the specification does not provide information on the prior application as indicated above under 'Priority'. Amendment to the first paragraph of the specification is requested.

(b) Certain recitations in the instant specification are not understood. See for example line 6 on page 27: "37□C"; "□ 105.6□F" at line 6 on page 28; line 3 on page 31: "pout".

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

7) Claims 1-10 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1 is vague and indefinite in the inconsistent recitations: "protection against disease" in line 1 and "protection against disease associated with infection by the antigen" in the last line. The two limitations are vague and confusing because of their differing scope.

(b) Claim 1 includes improper antecedence in the limitation: "the mixture of step (a)", because step (a) of the claim does not recite any "mixture".

(c) Claim 1 lacks a preceding article between the limitations "against disease". It is suggested that Applicants replace the recitation with --against a disease-- to obviate the rejection.

(d) Claim 2 lacks a preceding article between the limitations "causing disease". It is suggested that Applicants replace the recitation with --causing a disease-- to obviate the rejection.

(e) Claim 3 is incorrect in the recitations: "*pleuropneumonla*"; "*perfirengens*"; "*Pasterurella muitocida*"; "*Pasterurella*"; "*hyopneumonlae*" and "*Borella*".

(f) Claim 3 is confusing in limitations: "*Pasterurella muitocida*" (line 3) and "*Pasterurella multocida*". Do these represent two different bacteria?

(g) Claim 3 is in an improper Markush form because it does not recite the Markush species as: A, B, C etc. **and** K. The recitation --and-- is missing between the last two Markush species of claim 3.

(h) Claim 10 is confusing, incorrect and/or redundant in the recitation: "the administration of the orally administered vaccine into the mouth through a syringe". Correction is requested.

(i) Claim 3 is vague and indefinite in the use of abbreviated recitation "PRRS" in the

claim language. It is suggested that the abbreviation be recited as a full terminology at first occurrence, with its abbreviated recitation retained in parentheses.

(j) Claims 2-10, which depend directly or indirectly, from claim 1 are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. 102

8) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> **(a)** the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> **(e)** the invention was described in-
> **(1)** an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> **(2)** a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

9) Claim 1 is rejected under 35 U.S.C § 102(e) as being anticipated by Heo *et al.* (US 6,491,956) as evidenced by Bakal *et al.* (US 4,414,229).

Heo *et al.* disclosed a method of preventing and/or treating (i.e., protecting) *H. pylori* infection in a human by administering a composition comprising an effective amount of a bacterial antigen, *Lactobacillus acidophilus,* which is produced by admixing the bacterial antigen, *Lactobacillus acidophilus,* with a water soluble vehicle. The composition is a fortified liquid drinkable yogurt, buttermilk, cream cheese or ice cream (i.e., orally administered vaccine) containing water-soluble glucose, dextrose, fructose, lactose etc. See paragraph bridging columns 5 and 6; first and second full paragraphs in column 5; and first full paragraph in column 8.

That Heo's liquid yogurt or butter milk intrinsically contains water soluble palatable milk flavorant admixed in it is inherent from the teachings of Heo *et al.* in light of what is known in the art. For instance, Bakal *et al.* teach that skim milk contains a water soluble flavorant (see second full paragraph in column 3).

Claim 1 is anticipated by Heo *et al.*

10) Claims 1-3, 5 and 6 are rejected under 35 U.S.C § 102(e) as being anticipated by Casas *et al.* (US 6,100,388) as evidenced by Bakal *et al.* (US 4,414,229).

Casas *et al.* disclosed a method of vaccinating an animal for beneficially preventing, treating or protecting a diarrhoeal disease comprising administering said animal an orally administered *L. reuteri* vaccine expressing an antigen of enterotoxigenic *E. coli*, for example, K88 *E. coli*, a porcine pathogen. The vaccine is produced by combining the bacterial cells with a pharmaceutically acceptable excipient or a food product such as milk or yogurt for oral administration. The animal is an avian animal, i.e., inclusive of poultry. The method can be used in pharmaceutical and food industries for vaccination against pathogenic microorganisms. The vaccine is ingested by an animal in a pharmaceutically acceptable carrier or can be added to milk or milk products such as yogurt. See column 5, first full paragraph and lines 40-44; third full paragraph in column 4; column 12, lines 35-43; paragraphs bridging columns 4 and 5, columns 5 and 6, columns 14 and 15, and columns 15 and 16; Example II.

That Casas's milk or yogurt intrinsically contains water soluble milk flavorant admixed in it is inherent from the teachings of Casas *et al.* in light of what is known in the art. For instance, Bakal *et al.* teach that skim milk contains a water soluble flavorant (see second full paragraph in column 3).

Claims 1-3, 5 and 6 are anticipated by Casas *et al.*

11) Claims 1-3, 5, 6 and 9 are rejected under 35 U.S.C § 102(e) as being anticipated by Clements *et al.* (US 6,019,982) as evidenced by Bakal *et al.* (US 4,414,229).

Clements *et al.* disclosed a method of providing protection against an enterotoxic bacterial pathogen, such as, *Escherichia coli*, by administering an oral vaccine composition comprising the killed or attenuated whole cells of the pathogen and/or a mutant heat-labile enterotoxin. The vaccine comprises a microbial protective antigen such as *Escherichia coli* (a poultry pathogen), *Borrelia burgdorferi* (a canine pathogen), *Clostridium tetani*, *Salmonella typhimurium* (a poultry pathogen), *Brucella suis* (a porcine pathogen), *Leptospira icterohaemorrhagiae, Mycoplasma* sps. or parainfluenza virus, Reo virus, Parvo virus, or respiratory syncytial virus etc., The method is used in birds, immature and mature vertebrates, animal species, mammals and humans. The antigen composition is produced by combining the antigen(s) with a liquid pharmaceutical carrier

and a palatable flavoring agents for oral administration. The vaccine is further reconstituted with a substance such as milk. See sections 5 and 5.2 of the patent, particularly in columns 9-14 and fifth and sixth full paragraphs in column 4. That Clements' 'birds' are inclusive of poultry and that Clements' 'vertebrates' or 'animal species' are inclusive of swine or dogs is inherent from the teachings of Clements *et al.* since it is well known in the art that Clements' antigens, such as, *Salmonella typhimurium* or *Escherichia coli* are art-known poultry, swine or canine pathogens, *Borrelia burgdorferi* is an art-known canine pathogen, and *Brucella suis* is a art-known swine pathogen.

That Clements' milk intrinsically contains water soluble milk flavorant admixed in it is inherent from the teachings of Clements *et al.* in light of what is known in the art. For instance, Bakal *et al.* teach that skim milk contains a water soluble flavorant (see second full paragraph in column 3).

Claims 1-3, 5, 6 and 9 are anticipated by Clements *et al.*

Rejection(s) under 35 U.S.C. 103

12) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person. having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

13) Claims 1, 4, 6 and 7 are rejected under 35 U.S.C § 103(a) as being unpatentable over Casas *et al.* (US 6,100,388) or Clements *et al.* (US 6,019,982) in view of Grieve (*Poultry Digest*, November 1992, pp. 28-32 - Applicants' IDS).

The teachings of Casas *et al.* or Clements *et al.* are explained above, which do not disclose administration of the vaccine through drinking water.

However, it was routine at the time of the instant invention to carry out mass vaccination of poultry via drinking water. For instance, Grieve taught the routine, economical and time-effective mass vaccination of poultry through drinking water (see page 28).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to carry out Casas's or Clements' method of providing protection to poultry birds using drinking water vehicle as taught by Grieve to produce the instant invention with a reasonable expectation of success, since Grieve has shown it to be conventional, routine, economical and time-effective to administer a vaccine to poultry birds via drinking water. Choosing one art-known administration route or vehicle over another route or vehicle would have been obvious and is well within the realm of routine experimentation. One of skill in the art would have readily understood that administration of a vaccine via drinking water for mass vaccination is a matter of convenience, economy and time effectiveness.

Claims 1, 4, 6 and 7 are *prima facie* obvious over the prior art of record.

14) Claim 10 is rejected under 35 U.S.C § 103(a) as being unpatentable over Casas *et al.* (US 6,100,388) or Clements *et al.* (US 6,019,982) as modified by Grieve (*Poultry Digest*, November 1992, pp. 28-32 - Applicants' IDS) as applied to claims 1, 6 and 7 above, and further in view of Roland (US 6,399,074).

The reference of Roland is applied in this rejection because it qualifies as prior art under subsection (e) of 35 U.S.C § 102 and accordingly is not disqualified under U.S.C 103(a).

The teachings of Casas *et al.* or Clements *et al.* as modified by Grieve are explained above, which do not disclose the administration of the vaccine into the mouth through a syringe.

However, it was routine at the time of the instant invention to use a syringe for oral administration or vaccination of birds. For instance, Roland taught such a routine procedure (see lines 20-22 in column 18)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to carry out Casas's or Clements' method as modified by Grieve in poultry using Roland's feeding syringe to produce the instant invention with a reasonable expectation of

success, since Roland has shown it to be conventional and routine to administer a vaccine orally to birds using a syringe. Choosing one art-known administration method over another would have been obvious and is well within the realm of routine experimentation. One of skill in the art would have readily understood that oral administration of a vaccine using a syringe is a matter of convenience.

Claim 10 is *prima facie* obvious over the prior art of record.

15) Claim 8 is rejected under 35 U.S.C § 103(a) as being unpatentable over Clements *et al.* (US 6,019,982) as modified by Grieve (*Poultry Digest*, November 1992, pp. 28-32 - Applicants' IDS) as applied to claims 1, 6 and 7 above, and further in view of Frantz *et al.* (US 5,536,496).

The teachings of Clements *et al.* as modified by Grieve are explained above, which do not disclose the administration of *Erysipelothrix rhusiopathiae*-containing vaccine. However,

Clements *et al.* taught that their vaccine may contain and be administered with any biologically relevant antigen and/or vaccine, or killed or attenuated pathogens or relevant virulence determinants of specific pathogens. See paragraph bridging columns 9 and 10; and paragraph bridging columns 11 and 12.

Frantz *et al.* disclosed an *Erysipelothrix rhusiopathiae* bacterin or vaccine which is administered by any mode of administration or by any suitable route. The vaccine protected pigs from a challenge infection. See columns 20 and 21; see first full paragraph in column 5; and paragraph bridging columns 5 and 6.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use Frantz's *Erysipelothrix rhusiopathiae* bacterin or protective vaccine in Clements' method to produce the instant invention with a reasonable expectation of success, since Clements *et al.* expressly teach that any biologically relevant antigen and/or vaccine, or killed or attenuated pathogens or relevant virulence determinants of a specific pathogen can be used in their method. Given the teaching of Frantz *et al.* that their *Erysipelothrix rhusiopathiae* bacterin or protective vaccine is administered by any mode of administration or by any suitable route, one of skill in the art would have been motivated to produce the instant invention for the expected benefit of providing protection against *Erysipelothrix rhusiopathiae* disease in pigs or immature piglets.

Claim 8 is *prima facie* obvious over the prior art of record.

Relevant Prior Art

15) The prior art made of record and not relied upon currently in any of the rejections is considered pertinent to Applicants' disclosure:

- The addition of flavors or flavoring agents, such as, milk flavor, corn flavor, sucro-flavor, soy, anise, caramel, butterscotch, cheese and beef flavors to cattle feeds, swine feeds or poultry feeds and dog food or to water to enhance palatability for oral administration was well known and conventional in the art. For instance, see the disclosure of Tribble [*In*: *Feed Flavor and Animal Nutrition.* (ed) T.B. Tribble. Agriadis Inc., pp. 37-55, 1962 - Applicants' IDS].

Remarks

16) Claims 1-10 stand rejected.

17) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1 (CM1). The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which receives papers 24 hours a day and seven days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

18) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

January, 2003

SD
S. DEVI, PH.D.
PRIMARY EXAMINER